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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,112	12/31/2001	John J. Egan	361331-506	5381
30623	7590	01/11/2005		
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n N .

10/038,112

Applicant(s)

EGAN ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,9,11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,9,11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06/02/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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***D tailed Action***

1. Claims 1, 2, 4, 8, 9, 11 (13-17) are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al., RE38,330 E in view of EPA 0 458 589 A1 ('589).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 13-17 fall under the previous claim rejection under 35 USC 103(a) set forth in the office action mailed June 17, 2004. Additional comments concerning these claims will be made below.

***Response to Amendment(s)***

The following is responsive to Applicant's amendment received Oct. 18, 2004.

Claims 3, 5-7, 10, 12 are cancelled. New claims 13-17 are added. Claims 1, 2, 4, 8-9, 11, 13-17 are currently pending.

The previous claim objection(s) set forth in paragraph 1 of the office action mailed June 17, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous claim rejection under 35 USC 103(a), set forth in paragraph 2 of the office action mailed June 17, 2004 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed June 17, 2004 with the following additional comment:

It is Applicant's position that the Examiner has failed to establish a prima facie case of obviousness. One of ordinary skill in the art would not be motivated to combine

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the teachings of Cerami and Kabushiki (i.e. EP '589) to reach the present invention.

Furthermore, one of ordinary skill in the art when combining the teachings of Cerami and Kabushiki would have no reasonable expectation of success in achieving the claimed invention. Specifically, Applicant argues,

“Kabushiki does not cure the deficiencies of Cerami. Kabushiki merely discloses the combination of a cholinergic agent and a specific prostaglandin compound (13,14-dihydro-15-ketoprostaglandin) to treat ocular hypertension. Kabushiki does not teach or suggest thiazolium compounds. Further, one of ordinary skill in the art would readily recognize that the thiazolium compounds of the instant invention and prostaglandins are structurally distinct and possess very different biological activities.

Applicants submit that based on the structural and biological differences between the thiazolium compounds of Cerami and the prostaglandin family, one of ordinary skill in the art would not be motivated to combine Cerami and Kabushiki. As described above, there is no suggestion in either reference that would motivate a skilled artisan to modify the methods to decrease intraocular pressure using a combination of a thiazolium compound of formula 1 and a cholinergic agent. Finally, the skilled artisan would have no reasonable expectation of success combining the methods of using thiazolium compounds of Cerami with the prostaglandin/cholinergic compounds used in the methods of Kabushiki to reach the present invention.”

Said arguments have been considered but are not found to be persuasive.

Applicant's argument that Kabushiki teaches administering a combination of a prostaglandin and a cholinergic agent for lowering ocular pressure is noted. However, this does not negate the fact that Kabushiki discloses known, “commercialized” cholinergic agents for treating glaucoma such as pilocarpine. Please see page page 7, lines 9-10. Furthermore, since Kabushiki discloses that cholinergic agents when combined with prostaglandins are synergistically effective at lowering ocular pressure, one of ordinary skill in the art, absent evidence to the contrary, would reasonably expect cholinergic agents when combined with the thiazolium compound of Cerami to effectively reduce ocular hypertension suffered in the patients in Cerami et al.

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Therefore, the Examiner maintains that a proper prima facie case of obviousness has been made and the rejection is respectfully maintained.

With respect to new claims 13-14, the claimed compound is disclosed and obvious over the prior art for reasons already of record. Please refer to the office action mailed June 17, 2004. New claim 15 is taught by Kabushiki, which discloses pilocarpine as one of the "commercialized" cholinergic agents for treating glaucoma or ocular hypertension. Please see page 7, lines 9-10. New claim 16 is taught by Cerami at col. 10, lines 47-50. Finally, concerning claim 17, since Cerami discloses that administration may occur by other conventional means, it would have been obvious to one of ordinary skill in the art to further modify the method of the prior art by administering the compounds intra-camerally because one of ordinary skill in the art would reasonably expect intra-cameral administration to effectively deliver the compounds to the eye.

#### ***Conclusion***

Claims 1, 2, 4, 8, 9, 11, 13-17 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Dec. 29, 2004

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*Robert Fay*